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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/972,467 | 10/05/2001 | Leonard Buckbinder | PC10850B | 4966 |

7590 02/27/2002

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| EXAMINER | |
|---|---|
| HADDAD, MAHER M | |
| ART UNIT | PAPER NUMBER |
| 1644 | |

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/972,467 | BUCKBINDER ET AL. | |
| | Examiner | Art Unit | |
| | Maher M. Haddad | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: *See Continuation Sheet* .

DETAILED ACTION

1. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Maher Haddad, Art Unit 1644, Technology Center 1600.

***Sequence Compliance***

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

***Restriction Requirement***

3. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

4. The following is noted:

A) It is also noted that Claim 8 broadly recites "agonists" and "antagonists" that are utilized in the instant methods but does not require that these "agonists" and/or "antagonists" share *a substantial structural feature essential to a common utility*. The specification discloses that the agonist or antagonist compounds contain a hydroxamic acid moiety or an optionally substituted heterocyclic nucleus, or heteroaryl sulfonamide moiety, which compounds inhibit or stimulate the activity of endogenous or recombinant ADAMTS-SI (page 20, paragraph 5). The recited agonist or antagonists clearly differ in structure, and also differ in function since they act on different target molecules. Individual antagonists and agonists that do not share *a substantial structural feature essential to a common utility* are subject to restriction, rather than election of species (as per MPEP 803.02), within the context of the particular method.

The restriction has therefore been set forth for the methods encompassing each recited antagonist or antagonist as separate Groups, irrespective of the format of the claims.

Election of a group representing a generic "agonist" or "non-antibody antagonist" may be subject to an additional restriction requirement; if structurally distinct agonists or antagonists are introduced during the course of prosecution that do not share a substantial structural feature essential to a common utility with the elected agonist or antagonist.

5. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-2 and 5-7 and 15, drawn to an isolated polynucleotide SEQ ID NO: 2, expression system, host cells, and methods of producing the polypeptide, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 252.3, and 320.1.

II. Claims 3-4 and 15, drawn to a polypeptide encoded by SEQ ID NO: 2, fragments thereof, and heterologous proteins comprising said polypeptides; classified in Class 530, subclasses 350.

III. Claim 8, drawn to an agent as it reads on an antibody immunospecific for an ADAMST-SI polypeptide, classified in Class 530, subclasses 387.1.

IV. Claims 8 and 15, drawn to an agent as it reads on an agonist for an ADAMTS-SI, classified in Class 532, subclasses 1.

V. Claims 8 and 15, drawn to an agent as it reads on a *non-antibody* antagonist for an ADAMTS-SI, classified in Class 532, subclasses 1.

VI. Claim 8, drawn to an agent as it reads on a substrate for an ADAMTS-SI, classified in Class 532, subclasses 1.

VII. Claim 9, drawn to a method for treating a subject by administering an antibody immunospecific for an ADAMTS-SI, classified in Class 424, subclass 130.1.

VIII. Claims 9, and 14, drawn to a method for treating a subject by administering an agonist for an ADAMTS-SI, classified in Class 424, subclass 184.1.

IX. Claims 9, and 14, drawn to a method for treating a subject by administering a *non-antibody* antagonist for an ADAMTS-SI, classified in Class 424, subclass 184.1.

X. Claim 9, drawn to a method for treating a subject by administering a substrate for an ADAMTS-SI, classified in Class 514 subclass 8.

XI. Claim 10, drawn to a process for diagnosing a disease or a susceptibility to a disease in a subject comprising determining presence or absence of a mutation in a sample, classified in Class 435, subclass 6.

XII. Claim 11, drawn to a method for identifying a compound which antagonist and/or agonist to ADAMST-SI, classified in Class 435, subclass 7.1.

XIII. Claims 11 and 13, drawn to a method for identifying a compound which binds to ADAMST-SI, classified in Class 435, subclass 7.1.

XIV. Claim 12, drawn to a method for detecting a polynucleotide, classified in Class 435, subclass 6.

XV. Claim 14, drawn to a method for treating comprising administering a polypeptide, classified in Class 514, subclass 2.

XVI. Claim 14, drawn to a method for treating comprising administering a polynucleotide, classified in Class 514, subclass 44.

6. Groups I-VI are different products. Nucleic acids, polypeptides, antibodies to the polypeptides agonist/antagonist and substrate differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

7. Groups I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the protein can be made using an amino acid synthesizer.

8. Groups VII-XVI are different methods. A method for treating, a method for diagnosing, a method for diagnosing, a method for identifying, and a method for detecting differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

9. Groups I/XIV, I/XVI, II/XV, III/VII, IV/VIII, IV/XII, V/IX, V/XII, VI/X and VI/XIII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used for affinity purification, the poly nucleotide of Group I can be used to make a probe, and the protein of Group II can be used as an immunogen, in addition to the methods of treating, identification and detecting recited.

10. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

***Species Election***

11. This application contains claims directed to the following patentably distinct species of the claimed Inventions I-II: wherein the SEQ ID NO: 2 domain is:

A) metalloproteinase,
B) disintegrin domain,
C) prodomain, or
D) thrombospondin submotif.

These species are distinct because their structures and mode of actions are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. Claim 14 is generic to a plurality of disclosed patentably distinct species comprising Groups VII-X and XV-XVI: diseases. Applicant is required to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

13. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
February 20, 2002

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
2/21/02